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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/868,123

04/02/2002

Mary Collins

22058-514NATL

5639

7590

02/22/2006

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EXAMINER

DEBERRY, REGINA M

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 02/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/868,123

Applicant(s)

COLLINS ET AL.

Examiner

Regina M. DeBerry

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23,28,48-53,55-57,59-62 and 64-67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23,28,48-53,55-57,59-62 and 64-67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5/02, 2/03
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

Status of Application, Amendments and/or Claims

The amendment filed 01 December 2005 has been entered in full. Claims 1-22, 24-27, 29-47, 54, 58, 63 are cancelled.

Claims 23, 28, 48-53, 55-57, 59-62, 64-67 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections And/Or Rejections

The rejection to claims 28, 56, 58-62 under 35 USC 112, first paragraph, scope of enablement, as set forth at pages 3-5 of the previous Office Action (03 June 2005) is *withdrawn* in view of the amendment (01 December 2005).

The objection to claims 57, 64-67, as set forth at page 6 of the previous Office Action (03 June 2005) is *withdrawn* in view of the amendment (01 December 2005).

Priority

It is noted that priority to the applications listed in the first sentence of the specification, the application bib data sheet and the oath all fail to agree. Because it is unclear which application receives the appropriate priority, 12/13/99 is the effective filing date used for the purposes of applying prior art. Appropriate correction is required using the proper conditions set forth under 35 U.S.C. 120, 121 or 356(c) for receiving the benefit of the earlier filing date for the instant application.

Information Disclosure Statement

It is noted that the non-patent literature documents listed on the Information Disclosure Statement (IDS) submitted (09 May 2002 and 11 February 2003) have not been located and thus cannot be considered at this time. Only the U.S. Patent and Foreign Patent Documents will be considered.

New Claim Rejections - 35 USC § 112, First Paragraph, Written Description (New Matter)

Claims 23, 28, 48-53, 55-57, 59-62 and 64-67 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

The specification as originally filed does not provide support for the invention as now claimed: "...the portion of SEQ ID NO:3 that encodes about from about amino acid 26 to about amino acid 341 of SEQ ID NO:4.." (claims 23 and 28) and "...wherein said polypeptide comprises from about amino acid 26 to about amino acid 341 of SEQ ID NO:4" (claims 48, 59 and 64).

Applicant's amendment, filed 13 July 2004, asserts that no new matter has been added and directs support to page 4, lines 21-26 and page 9, lines 20-23 for the written

description for the above-mentioned "limitations". However, the wording or connotation of the instant claims is not readily apparent from said sections.

The specification as filed does not provide a written description or set forth the metes and bounds of this "limitations". The instant claims now recite limitations which were not clearly disclosed in the specification as filed, and now change the scope of the instant disclosure as-filed. Applicant is required to cancel the new matter in the response to this Office action. Alternatively, Applicant is invited to provide specific written support for the "limitations" indicated above or rely upon the limitations set forth in the specification as filed.

New Claim Rejections - Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 23, 28, 48, 55, 57, 59, 64 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 6-8 and 14 of U.S. Patent No. 6,248,714 B1 in view of Cookson *et al.*, US 6,387,615 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other. Instant claims 23, 48, 55 and claim 1 of patent '714 are both drawn to a method of inhibiting binding of IL-13 to the IL-13 receptor in a mammalian subject comprising, administering a polypeptide comprising amino acids 26 to 341 of SEQ ID NO:4. Water is considered a pharmaceutically acceptable carrier. Claims 6-8 and 14 of patent '714 are drawn to a method of treating an Ig-mediated condition in a mammal comprising administering a protein comprising the amino acid sequence comprising 26 to 341 of SEQ ID NO:4. Instant claims 28, 57, 59, 64 are drawn to a method of treating asthma in a mammalian subject comprising administering a polypeptide comprising amino acids 26 to 341 of SEQ ID NO:4. Cookson *et al.* teach that most asthma in children and young adults is initiated by IgE mediated allergy to inhaled allergens (column 1, lines 10-24 and lines 34-46). The genus of treating an Ig-mediated condition (patent '741) renders the species of IgE mediated condition (asthma, instant claims) obvious.

New Claim Rejections - 35 USC § 102(b)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 23, 28, 48-53, 55-57, 59-62, 64-67 are rejected under 35 U.S.C. 102(b) as being anticipated by **Collins et al., US Patent 5,710,023** (reference submitted by Applicant). Collins et al. teach SEQ ID NO:3 as the human cDNA of IL-13 binding chain of IL-13 receptor and SEQ ID NO:4 as the human protein of IL-13 binding chain of IL-13 receptor (column 3, line 60-column 4, line 28). Collins et al. teach pharmaceutical compositions comprising a fusion protein, amino acids 26 to 341 of SEQ ID NO:4 and an Fc fragment (column 2, lines 22-42 and column 3, lines 1-15). Collins et al. teach methods of inhibiting binding of IL-13 to IL-13 receptor in a mammalian subject comprising administering a therapeutically effective amount of a composition comprising IL-13bc (column 3, lines 39-45). Collins et al. teach the administration of IL-13bc for the treatment of asthma (column 8, lines 1-10).

New Claim Rejections - 35 USC § 102(e)

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 23, 28, 48-53, 55-57, 59-62, 64-67 are rejected under 35 U.S.C. 102(e) as being anticipated by **Collins et al., US Patent 6,248,714 B1**.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in

the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Collins *et al.* teach SEQ ID NO:3 as the human cDNA of IL-13 binding chain of IL-13 receptor and SEQ ID NO:4 as the human protein of IL-13 binding chain of IL-13 receptor (column 4, lines 1-28). Collins *et al.* teach pharmaceutical compositions comprising a fusion protein, amino acids 26 to 341 of SEQ ID NO:4 and an Fc fragment (column 2, lines 30-49 and column 3, lines 1-22). Collins *et al.* teach methods of inhibiting binding of IL-13 to IL-13 receptor in a mammalian subject comprising administering a therapeutically effective amount of a composition comprising IL-13bc (column 3, lines 45-50 and claims). Collins *et al.* teach the administration of IL-13bc for the treatment of asthma (column 8, lines 7-20 and claims).

Claims 23, 28, 48-53, 55-57, 59-62, 64-67 are rejected under 35 U.S.C. 102(e) as being anticipated by **Collins *et al.*, US Patent 6,268,480 B1.**

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Collins *et al.* teach SEQ ID NO:3 as the human cDNA of IL-13 binding chain of IL-13 receptor and SEQ ID NO:4 as the human protein of IL-13 binding chain of IL-13

receptor (column 4, lines 1-30). Collins *et al.* teach pharmaceutical compositions comprising a fusion protein, amino acids 26 to 341 of SEQ ID NO:4 and an Fc fragment (column 2, lines 30-65; column 3, lines 1-22 and claims). Collins *et al.* teach methods of inhibiting binding of IL-13 to IL-13 receptor in a mammalian subject comprising administering a therapeutically effective amount of a composition comprising IL-13bc (column 3, lines 45-50). Collins *et al.* teach the administration of IL-13bc for the treatment of asthma (column 8, lines 7-20).

Claims 23, 28, 48-53, 55-57, 59-62, 64-67 are rejected under 35 U.S.C. 102(e) as being anticipated by **Collins *et al.*, US Patent 6,214,559 B1.**

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Collins *et al.* teach SEQ ID NO:3 as the human cDNA of IL-13 binding chain of IL-13 receptor and SEQ ID NO:4 as the human protein of IL-13 binding chain of IL-13 receptor (column 4, lines 16-30). Collins *et al.* teach pharmaceutical compositions comprising a fusion protein, amino acids 26 to 341 of SEQ ID NO:4 and an Fc fragment (column 2, lines 30-65; column 3, lines 1-22). Collins *et al.* teach methods of inhibiting binding of IL-13 to IL-13 receptor in a mammalian subject comprising administering a

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therapeutically effective amount of a composition comprising IL-13bc (column 3, lines 45-50). Collins *et al.* teach the administration of IL-13bc for the treatment of asthma (column 8, lines 7-20).


Conclusion

No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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2/15/06


MARIANNE P. ALLEN
PRIMARY EXAMINER
AU 1647

2/17/06